Course Objectives:
The purpose of the research design and development series is to build upon the skills learned in the intensive summer session and provide a hands-on research experience. Trainees will learn the phases of the research process from conception, to design, and ultimately, implementation of the research. Through a combination of group seminars and independent work, and using a topic of their own research choice, trainees will develop their own research proposal in the form of an NIH grant application, including specific aims, background and significance, prior work and methods sections. In addition, trainees will review and critique the work of their peers.

Course Requirements:
Course requirements are divided into 2 broad categories: products and documents related to the development of the trainees own research proposal and written reviews and critiques of others work. The culmination of these assignments is the production of a submitable NIH or equivalent research proposal.

A summary of the content of each class session and due dates for assignments is included in the last page of this syllabus.

Course Mechanics:
The most up to date course information and announcements will be available sent via e-mail from the faculty or a member of the CRTP Administrative team. Assignments must be sent by the date indicated in this syllabus to crtp@pitt.edu.

Note: The class sessions with a shaded title are lecture sessions. The class sessions with a non-shaded title are small group sessions.

Updated 7/30/02
### Session 2 9/09/03  
**Research Goals into Specific Aims: Focusing a research project**  
Pilkonis

**Concepts and Topics:**  
This session will introduce the participants to issues relating to the conversion of a clinical issue into an answerable research question.

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment:**

### Session 2b 9/09/03  
**Overview of the NIH**  
Pilkonis

**Concepts and Topics:**
1. Research training and development timetable
2. Overview of NIH grant mechanisms
   - K (career development) awards vs. R (research) awards
3. Overview of NIH review process
   - Review criteria
   - IRG boundaries and rosters

**Required Reading:** (prior to session)
1. HHS Agencies ([www.hhs.gov/agencies](http://www.hhs.gov/agencies))
2. NIH: Institutes, Centers and Offices ([www.nih.gov/icd](http://www.nih.gov/icd))
4. Cartoon: Nine types of PIs

### Session 3 9/16/03  
**Review of Existing Grants**  
Individual Group Leaders

**Concepts and Topics:**
1. During this session each group will individually review the NIH grant distributed in session 1. Primary and secondary reviewers will bring written reviews to lead discussion. In this initial evaluation, the clarity, design and impact of the grant will be discussed
2. Distribute grants for Mock Study Section in Session 6 and 7. Grant reviewers assigned.

**Required Reading:** (prior to session)
- Assigned grant handed out in session 1

**Homework Assignment:**

1. **Assigned Reviewers**- Primary and Secondary reviewers will need to mail their written grant review (3-4 pages) per NIH review format for the Mock Study Sections in Session 6 and 7 (10/7 and 10/14/03) prior to discussion to crtp@pitt.edu.
2. **All Trainees** - Come to Session 6 & 7 prepared to discuss the grant.

**DUE:**
- **Assigned Reviewers** – Primary and secondary reviewers mail their written grant review to crtp@pitt.edu by 9/16/03 prior to the class time and discussion.

### Session 4a 9/23/03  
**Specific Aims and Specific Hypotheses: From the general to the detailed**  
Pilkonis

**Concepts and Topics:**
1. Differences between hypothesis driven research and descriptive or investigative aims
2. Linking hypotheses to aims
3. Converting a specific aim into a series of tasks or hypotheses

**Required Reading: (prior to session)**

**Optional Reading:**

**Homework Assignment:**

<table>
<thead>
<tr>
<th>Session</th>
<th>Date</th>
<th>Description</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>4b</td>
<td>9/23/03</td>
<td>PHS 398</td>
<td>Pilkonis</td>
</tr>
</tbody>
</table>

**Concepts and Topics:**

This session will review and describe the overall structure of an NIH grant, and the components expected in PHS form 398

**Required Reading: (prior to session)**

1. Instructions for PHS 398

**Optional Reading:**

**Homework Assignment:**

<table>
<thead>
<tr>
<th>Session</th>
<th>Date</th>
<th>Description</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>9/30/03</td>
<td>NIH Grant Review Process</td>
<td>Pilkonis</td>
</tr>
</tbody>
</table>

**Concepts and Topics:**

**Required Reading: (prior to session)**

2. CSR organizational Chart ([www.csr.nih.gov/welcome/orgchart.htm](http://www.csr.nih.gov/welcome/orgchart.htm))

**Optional Reading:**

**Homework Assignment:**

<table>
<thead>
<tr>
<th>Session</th>
<th>Date</th>
<th>Description</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>10/07/03</td>
<td>Mock Study Section (Session #1)</td>
<td>Individual Group Leaders</td>
</tr>
</tbody>
</table>

**Concepts and Topics:**

It is critically important to understand and appreciate the grant review process. This hands-on session will provide realistic understanding of study section mechanics, operation and the variety of opinion regarding the validity of the grant proposal.

**Required Reading: (prior to session)**

Assigned grant handed out in session 3

**Homework Assignment:**

1. **All Trainees** - 1 page Specific Aims section describing his or her research will need to be sent to crtp@pitt.edu at least 3 days prior to the day of presentation (10/21/03 or 10/28/03) in either Session 8 or 9.

2. **Assigned Reviewers** - Individuals will be assigned to read and critique a presenter’s Specific Aims section. 1 Page written critique is due at the end of the day that the proposal is presented.

**DUE:**

- **Assigned Reviewers** - Primary and Secondary reviewers will send (to crtp@pitt.edu) a written grant review (3-4 pages) per NIH review format for the Mock Study Sections by 10/7/03 prior to class time and discussion.
Session 7 10/14/03  Mock Study Section (Session #2)  Individual Group Leaders

Concepts and Topics:
It is critically important to understand and appreciate the grant review process. This hands-on session will provide realistic understanding of study section mechanics, operation and the variety of opinion regarding the validity of the grant proposal.

Required Reading: (prior to session)
Assigned grant handed out in session 3

Homework Assignment:

DUE:
- Assigned Reviewers- Primary and Secondary reviewers send to crtp@pitt.edu a written grant review (3-4 pages) per NIH review format for the Mock Study Sections by 10/07/03 prior to class time and discussion.

Session 8 10/21/03  Individual Groups: Presentation of Specific Aims (Session #1)  Individual Group Leaders

Session 9 10/28/03  Individual Groups: Presentation of Specific Aims (Session #2)  Individual Group Leaders

Concepts and Topics:
The specific aims section presents in succinct, clear language the overall goals of the research, and the specific questions that the research will answer. An individual reading the specific aims should be able to understand the importance of the question, the basic design the study will use to answer the question, and preferably the implication of the results of successful completion of the study.

Required Reading: (prior to session)
Each participant should read the 1-page specific aims of the co-participants who will be presenting that particular day

Homework Assignment:

1. All Trainees - 1 to 2 page write up of Revised Specific Aims will need to be sent to crtp@pitt.edu least 3 days prior (11/8/03 or 11/15/03) to the day of presentation. 1 power point slide stating goal and specific aims statement is required.

DUE:
- Presenters - Completed 1 Page Specific Aims section - Each presenter send to crtp@pitt.edu a 1-page Specific Aims section describing his or her research by 10/18/03 or 10/24/03 depending on assigned day of presentation. No more than 10 slides for in class presentation of Specific Aims.
- Assigned Reviewers - Written Review of Classmates’ Specific Aims Section - Individuals assigned to read and critique a presenter’s Specific Aims section will electronically post a 1 page written critique by the end of the day the proposal is presented.

Session 10 11/04/03  Specific Aims Branch

Concepts and Topics:
1. Goal statement
2. Specific aim statements
3. Specific aim as the primary scaffold for a grant proposal
4. Designing a scaffold for the grant
<table>
<thead>
<tr>
<th>Session 11</th>
<th>11/11/03</th>
<th>Revised Specific Aims Presentations</th>
<th>Individual Group Leaders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 12</td>
<td>11/18/03</td>
<td>Revised Specific Aims Presentations</td>
<td>Individual Group Leaders</td>
</tr>
</tbody>
</table>

**Concepts and Topics:**
Revised specific Aims Presentations in small groups

**Required Reading:** *(prior to session)*
Each participant should read the 1-page Revised Specific Aims of the co-participants who will be presenting that particular day

**Homework Assignment:**

**DUE:**
- All Trainees - 1 to 2 page write up of Revised Specific Aims to send crtp@pitt.edu by 11/9/02 or 11/16/02, depending on assigned day of presentation, 1 power point slide stating goal and specific aims statement

<table>
<thead>
<tr>
<th>Session 13</th>
<th>11/25/03</th>
<th>Linking Aims to Methods</th>
<th>Branch</th>
</tr>
</thead>
</table>

**Concepts and Topics:**
1. Use of Specific Aims statement in grant structure
2. Application to design
3. Application to statistical analysis
4. Application to selection criterion
5. Requirements of Preliminary Methods Section

**Required Reading:** *(prior to session)*

**Homework Assignment:**

1. Presenters: Study Design section will need to be sent to crtp@pitt.edu at least 3 days prior (12/14/02 or 1/4/03) to the day of presentation
2. All Trainees: Written Review of Classmates’ Study Design section - Individuals will be assigned to read and critique a presenter’s Study Design section. 1 Page written critiques will need to be sent to crtp@pitt.edu by the end of the day the proposal is presented.

<table>
<thead>
<tr>
<th>Session 14a</th>
<th>12/02/03</th>
<th>Developing a Research Program</th>
<th>Pilkonis</th>
</tr>
</thead>
</table>

**Concepts and Topics:**

**Required Reading:** *(prior to session)*
1. Succeeding in Science: Some Rules of Thumb
2. Sounding Board: Picking a Research Problem – The Clinical Decision
3. The Foundation Center ([http://grants.nih.gov/training/extramural.htm](http://grants.nih.gov/training/extramural.htm))
4. NIH Research Training Opportunities ([http://grants.nih.gov/training/extramural.htm](http://grants.nih.gov/training/extramural.htm))

<table>
<thead>
<tr>
<th>Session 14b</th>
<th>12/02/03</th>
<th>Types of NIH Grant Awards</th>
<th>Pilkonis</th>
</tr>
</thead>
</table>

**Concepts and Topics:**

**Required Reading:** *(prior to session)*
1. Applying for NIH Grants

**Optional Reading:**
### Homework Assignment:

**Session 15**  12/09/03  Pre-Award Grant Processes  Pilkonis

**Concepts and Topics:**
1. A Case Based Approach For Estimating Costs in Psychosocial Research
2. What’s the Price if a Research Subject? Approaches to Payment for Research Participation

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment:**

**Session 16**  12/16/03  Preliminary Study Design Presentations  Individual Group Leaders

**Session 17**  1/06/04  Preliminary Study Design Presentations  Individual Group Leaders

**Concepts and Topics:**
Each individual will present a ½ hour detailed summary of the study design through which they will conduct their proposed research.

**Required Reading:** (prior to session)
Each trainee should read the Study Design section of the co-participants who will be presenting that particular day

**Homework Assignment:**

**DUE:**
- **Presenters** - Study Design section sent to crtp@pitt.edu by 12/14/03 or 1/4/04 depending on assigned day of presentation
- **All Trainees** - Written Review of Classmates’ section - Individuals assigned to read and critique a presenter’s Study Design section will need to be sent to crtp@pitt.edu by the end of the day the proposal is presented.

**Session 18**  1/13/04  Revised Study Design Presentations  Individual Group Leaders

**Concepts and Topics:**
Revised Study Design Presentations in small groups

**Required Reading:** (prior to session)
Each participant should read the Revised Study Design of the co-participants who will be presenting that particular day

**Homework Assignment:**

**DUE:**
- **All Trainees** –Revised Study Design will need to be sent to crto@pitt.edu by 1/11/02. 1 power point slide stating goal and specific aims statement for 10 minute in class presentation.

**Session 19a**  1/20/04  Information Technology  TBN

1. **Concepts and Topics:**
Homework Assignment:

1. **Presenters** – Prior Work/Feasibility section will need to be sent to crtp@pitt.edu at least 3 days prior (1/24/04 or 1/30/04) to the day of presentation.

2. **All Trainees** – Written review of classmates’ Prior Work/Feasibility section – Individuals will be assigned to read and critique a presenter’s section. 1 page written critiques will need to be sent to crtp@pitt.edu by the end of the day the proposal is presented.

### Concepts and Topics

<table>
<thead>
<tr>
<th>Session 19b</th>
<th>1/20/04</th>
<th>Budget Preparation</th>
<th>TBN</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Session 20</th>
<th>1/27/04</th>
<th>Prior Work/Feasibility Presentations</th>
<th>Individual Group Leaders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 21</td>
<td>2/3/04</td>
<td>Prior Work/Feasibility Presentations</td>
<td>Individual Group Leaders</td>
</tr>
</tbody>
</table>

**Concepts and Topics:**

Each individual will present a ½ hour detailed summary of the Prior Work/Feasibility section of grant proposal.

**Required Reading:** (prior to session)

Each trainee should read the Prior Work/Feasibility section of the co-participants who will be presenting that particular day.

### Concepts and Topics:

An important aspect of setting the stage for a successful research application is the systemic understanding of the current state of knowledge regarding the particular problem under study.

1. Constraints of space versus breadth of topic
2. How to focus
3. What to select
4. An opportunity in patient oriented research

### Homework Assignment:

1. **Presenters** – Background and Significance section will need to be sent to crtp@pitt.edu at least 3 days prior (2/14/04 or 2/21/04) to the day of presentation.

2. **All Trainees**: Written Review of Classmates’ Background and Significance section - Individuals will be assigned to read and critique a presenter’s Background and Significance section. 1 Page written critiques will need to be sent to crtp@pitt.edu by the end of the day the proposal is presented.

**DUE:**

- **Presenters** – Prior Work/Feasibility section sent to crtp@pitt.edu by 1/24/04 or 1/30/04 depending on assigned day of presentation.
- **All Trainees**: Written Review of Classmates’ Prior Work/Feasibility section - Individuals assigned to read and critique a presenter’s section will need to sent their 1 Page written critique to crtp@pitt.edu by the end of the day the proposal is presented.
| Session 23 | 2/17/04 | Background and Significance Presentation | Individual Group Leaders |
| Session 24 | 2/24/04 | Background and Significance Presentation | Individual Group Leaders |

**Concepts and Topics:**
Each individual will present a ½ hour detailed summary of the Background and Significance section of the grant proposal.

**Required Reading: (prior to session)**
Each trainee should read the Background and Significance section of the co-participants who will be presenting that particular day.

**Homework Assignment:**
1. **Presenters** - Preliminary Research Grant Proposal will need to be sent to crtp@pitt.edu at least 10 days prior (3/13/04 or 3/20/04) depending on assigned day of presentation.
2. **All Trainees** - Written Review of Classmates’ Preliminary Research Grant Proposal - Individuals will be assigned to read and critique a presenter’s Preliminary Research Grant Proposal section must send their 1 Page written critique to crtp@pitt.edu by the end of the day the proposal is presented.

**DUE:**
- **Presenters** – Background and Significance section sent to crtp@pitt.edu by 2/14/04 or 2/21/04 depending on assigned day of presentation.
- **All Trainees**: Written Review of Classmates’ Background and Significance section - Individuals assigned to read and critique a presenter’s Background and Significant section must send their 1 Page written critique to crtp@pitt.edu by the end of the day the proposal is presented.

### CLRES 2050 3/2/04
**Working with the IRB**
Dennis Swanson

**Concepts and Topics:**

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment:**

| CLRES 2050 | 3/9/04 | Discussion of Sample IRB Protocols | David Barnard |

**Concepts and Topics:**

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment:**

| CLRES 2050 | 3/16/04 | Scientific Integrity and Misconduct | Jerry Rosenberg |

**Concepts and Topics:**

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment:**

| Session 25 | 3/23/04 | Preliminary Presentation Final Project | Individual Group Leaders |
| Session 26 | 3/30/04 | Preliminary Presentation Final Project | Individual Group Leaders |

**Concepts and Topics:**
Trainees will present Preliminary Research Grant Proposal, bring up and discuss analytic problems, etc.

**Required Reading: (prior to session)**

**Optional Reading:**
Homework Assignment: Homework Assignment:

DUE:

- **Presenters** - Preliminary Research Grant Proposal to be sent to crtp@pitt.edu 3/13/04 or 3/24/04 depending on assigned day of presentation.
- **All Trainees**: Written Review of Classmates’ Preliminary Research Grant Proposal - Individuals assigned to read and critique a presenter’s Preliminary Research Grant Proposal section must send their 1 Page written critique to crtp@pitt.edu by the end of the day the proposal is presented.

<table>
<thead>
<tr>
<th>CLRES 2050</th>
<th>4/6/04</th>
<th>Informed Consent</th>
<th>Barnard</th>
</tr>
</thead>
</table>

**Concepts and Topics:**

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment:**

1. **All Trainees** – A summary of the confidentiality and patient protection aspects of their proposal, in a formal IRB application format to be presented.

<table>
<thead>
<tr>
<th>CLRES 2050</th>
<th>4/13/04</th>
<th>Randomized Clinical Trials</th>
<th>Barnard</th>
</tr>
</thead>
</table>

**Concepts and Topics:**

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment:**

1. **All Trainees** – A summary of the confidentiality and patient protection aspects of their proposal, in a formal IRB application format will need to be sent to crtp@pitt.edu at least 3 days prior (4/24/04 or 5/1/04) to the day presentation for the Mock IRB.

<table>
<thead>
<tr>
<th>CLRES 2050</th>
<th>4/20/04</th>
<th>Special Populations</th>
<th>Barnard</th>
</tr>
</thead>
</table>

**Concepts and Topics:**

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment:**

1. **All Trainees** – A full PHS-398 formulated grant application will need to sent to crtp@pitt.edu at least 10 days prior (5/1/04 or 5/8/04) to the day of presentation.
2. **Assigned Reviewers**: Written Review of the proposal in NIH format with score - Individuals will be assigned to be primary and secondary reviewers. 3-4 Page written review of the proposal along with a score will need to be sent to crtp@pitt.edu by the end of the day the day after the proposal is presented.

<table>
<thead>
<tr>
<th>CLRES 2050</th>
<th>4/27/04</th>
<th>Mock IRB</th>
<th>Barnard</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>CLRES 2050</th>
<th>5/4/04</th>
<th>Mock IRB</th>
<th>Barnard</th>
</tr>
</thead>
</table>

**Concepts and Topics:**

Each individual will present a summary of the confidentiality and patient protection aspects of their proposal, in a formal IRB application format. This session will be conducted by Dr. Barnard once in each group, and will change timing based on the group with session 27 and 28.

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment**

DUE:
- **All Trainees** – A summary of the confidentiality and patient protection aspects of their proposal, in a formal IRB application format sent to crtp@pitt.edu by 4/24/04 or 5/1/04 depending on assigned day of presentation.

<table>
<thead>
<tr>
<th>Session</th>
<th>Date</th>
<th>CRTP Grant Study Section</th>
<th>Individual Group Leaders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 27</td>
<td>5/11/04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Session 28</td>
<td>5/18/04</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Concepts and Topics:**

These sessions provide the culmination of the work of the seminar series. Each participant will submit a full PHS-398 formulated grant application at least 10 days prior to the session that it will be presented. Class participants will take roles as primary, secondary reviewers, and will provide an oral critique of the grant, as well as submit a written review of the proposal in NIH format with score.

**Required Reading:** (prior to session)

**Optional Reading:**

**Homework Assignment:**

**DUE:**

- **All Trainees** - Each participant will submit a full PHS-398 formulated grant application by 5/1/04 or 5/8/04 depending on assigned day of presentation.
- **Assigned Reviewers:** Written Review of the proposal in NIH format with score - Individuals assigned to be primary and secondary reviewers will need to send critiques to crtp@pitt.edu by the end of the day the day after the proposal is presented.

<table>
<thead>
<tr>
<th>Session 32</th>
<th>Date</th>
<th>CRTP Seminar Wrap</th>
<th>Faculty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Session 32</td>
<td>5/25/04</td>
<td>CRTP Seminar Wrap</td>
<td>Faculty</td>
</tr>
</tbody>
</table>
### Description of Written Assignments

<table>
<thead>
<tr>
<th>Individual Project Related Assignments</th>
<th>Peer Review Related Assignments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1</strong> Completed 1 page specific aims section</td>
<td>A Written review of assigned grant for existing grant review session</td>
</tr>
<tr>
<td><strong>2</strong> Completed Revised Specific Aims</td>
<td>B Written review of assigned grant for mock study section</td>
</tr>
<tr>
<td><strong>3</strong> Completed preliminary study design section</td>
<td>C Written review of classmates’ specific aims section</td>
</tr>
<tr>
<td><strong>4</strong> Completed background and significance section</td>
<td></td>
</tr>
<tr>
<td><strong>5</strong> Completed prior work section/IRB proposal</td>
<td>D Written review of classmates’ preliminary methods section</td>
</tr>
</tbody>
</table>

### Group Leaders/Locations

<table>
<thead>
<tr>
<th>Group Leaders/Locations</th>
<th>Key</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert Branch, MD</td>
<td>Grey: Lecture for all students</td>
</tr>
<tr>
<td>MUH GCRC 8 North, N864</td>
<td></td>
</tr>
<tr>
<td>Kevin Kraemer, MD</td>
<td>White: Small groups meet</td>
</tr>
<tr>
<td>230 McKee Place, room 600.08</td>
<td></td>
</tr>
<tr>
<td>Bill Gardner, PhD</td>
<td></td>
</tr>
<tr>
<td>230 McKee Place, room 600.37</td>
<td></td>
</tr>
<tr>
<td>Step</td>
<td>Task</td>
</tr>
<tr>
<td>------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td>6</td>
<td>Completed Preliminary Research Grant Proposal</td>
</tr>
<tr>
<td>7</td>
<td>Formal IRB Application</td>
</tr>
<tr>
<td>8</td>
<td>Completed Final research Grant Proposal</td>
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</table>